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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,453	09/25/2003	William T. Donofrio	END 5028	5508

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EXAMINER

LOPEZ, AMADEUS SEBASTIAN

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/670,453	Applicant(s) DONOFRIO, WILLIAM T.	
	Examiner Amadeus S. Lopez	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The examiner has considered all references disclosed within the information disclosure statement filed on 7/12/2004.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. **Claims 1-9 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6807965 to Hickie in view of US Patent Application Publication No. 2003/0189492 to Harvie.**
3. **With regards to claims 1, 17, and 19, what is taught and shown by Hickie is a conscious sedation system comprising: a) a controller (14) which generates a request for a predetermined response from a patient and which analyses at least a response**

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made by the patient to the request to determine a level of sedation of the patient (Col. 21); and b) a facemask (30) which is disposable on the face of the patient proximate at least one of the nose and the mouth of the patient; and c) a response testing apparatus including: 1) a request assembly (one embodiment is disclosed as 313; Col. 23, lines 39-58) which communicates to the patient the request generated by the controller (Col. 21-25); and 2) a response assembly (one embodiment is disclosed as 307) which senses the response and which communicates the response to the controller (14) which analyses at least the response to determine a level of sedation of a patient (Claim 1).

What is not disclosed by Hickie is a nasal cannula for monitoring the breathing of a patient, wherein at least part of at least one of the request and response assemblies is supported by the cannula. Hickie teaches a facemask. It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the breathing facemask (30) of Hickie for the nasal cannula device as taught by Harvie because it is obvious that one breathing apparatus means can be replaced for another. It is also well known in the art to use a nasal cannula such as that taught by Harvie to monitor the breathing of a patient. Please refer to paragraphs 39 and 41 of US Patent Application Publication No. 2005/0059924 to Katz et al that teaches a nasal cannula for monitoring the breathing of a patient. Further what is not taught by Hickie is wherein at least one of the request and response assemblies is supported by cannula. Hickie teaches a request assembly in which a vibrator is located in palm support portion 303 (Col. 23, lines 51-54) to query a response from a user. What is taught by Harvie is a nasal cannula with a vibratory means disposed thereon (Paragraph 31). Therefore it

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would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a vibrator disposed on a nasal cannula because it is well known in the art as taught by Harvie.

4. **With regards to claims 2 and 18**, what is taught and shown by Hickie is a conscious sedation system wherein a user and/or the controller determines a delivery schedule of a conscious-sedation drug to the patient based on at least in part of the determined level of sedation of the patient (Col. 21, lines 8-56). Hickie discloses that ACQ system generates signals to reflect the amount of time it took for the patient to activate response device 266 in response to query initiate device 264. Controller 14 then can use these signals to generate an instruction in response thereto to maintain or decrease the level of sedation (Col. 25, lines 5-30)

5. **With regards to claims 3, 5, 6, and 20** what is taught and shown by Hickie is a conscious sedation system with all the limitations of claim 3 with the exception of wherein the request assembly includes a first vibrator supported by, disposed in, or disposed on the cannula. What is taught and shown by Harvie is a vibrator supported by and disposed on the cannula (Paragraph 31). Harvie states that the vibrator can be incorporated in other items such as a nasal cannula and can be broadly interpreted to mean that it is capable of being disposed in the cannula. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the sedation system of Hickie by replacing the vibration means in the hand held device for a vibration means located on or in a nasal cannula because it is well known in the art

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to have a vibration means disposed on/in a nasal cannula and therefore obvious to replace one vibration means for another.

6. **With regards to claim 4**, what is taught by Hickie is a conscious sedation system with all the limitations of claim 4 with the exception of wherein the first vibrator produces a tactile response to the face of the patient. What is taught by Hickie is a vibrator located within a palm support portion 303 of a hand held device. What is taught by Harvie is having a vibration means located on a nasal cannula. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the sedation system of Hickie by replacing the vibration means in the hand held device for a vibration means located on or in a nasal cannula because it is well known in the art to have a vibration means disposed on/in a nasal cannula and therefore obvious to replace one vibration means for another. With this modification, the vibrator would in fact produce the tactile response to the face of the patient.

7. **With regards to claim 7 and 8**, what is taught by Hickie is a conscious sedation system with all the limitations of claim 7 with the exception of wherein the request assembly includes a second vibrator disposable to produce a tactile request to a site on the patient other than to the face of the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a second vibrator, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art.

8. **With regards to claim 9**, what is taught by Hickie is the use of one vibrator of the request assembly producing a tactile response (Col. 23).

9. Claims 10-16, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickie in view of Harvie as applied to claim` above, and further in view of US Patent No. 6024088 to Ishikawa et al.

10. With regards to claims 10-16, 21, and 22 what is taught and shown by Hickie is a conscious sedation system with all the limitations of the claims with the exception of wherein the predetermined response is a patient head-generated response which is further a patient-generated breathing response, and wherein at least a part of the response assembly includes a breathing sensor and/or a breathing-detection tube supported by the cannula. What is taught by Ishikawa et al is that it is well known in the art to have a breath sensor disposed in a nasal cannula attached to the nose of a patient to control the supply of oxygen in response to electrical signals that corresponds to the breathing parameters of a user sent from the breath sensor (Col. 1, lines 20-34). This breathing sensor is fully capable of detecting a breathing response that includes a yawn, a breath deeper than an impervious breath, and the pressure of the exhaled breathing of a patient because it is well known in the art that breathing sensors detect all aspects of a breath including most importantly pressure and flow which would correspond to the listed scenarios. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the nasal cannula vibratory response assembly to include a breathing sensor supported by the nasal cannula to have the actions of the controller in response to the patient's level of sedation correspond to the breathing parameters of a user because this sensing means is more accurate than having the controller respond to a physical or verbal response of

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a user. Hickie does not disclose a conscious sedation system wherein the patient generated response is a patient generated vocal response, or a patient generated head movement response, wherein the response assembly includes a sound detector or motion sensor supported by the cannula. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to use a motion or sound detector to detect a patient generated response consisting of a verbal or head movement response because the applicant has not disclosed that these means provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art furthermore, would have expected that the conscious sedation system as taught by Hickie in view of Harvie in further view of Ishikawa et al that utilizes the breathing sensor means within a nasal cannula to perform equally well with either the motion/sound detection means because both would perform the same function of taking a patient generated response and having the controller use that response to detect a level of sedation.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Amadeus S Lopez
Examiner
Art Unit 3743
August 8, 2006

ASL


Henry Bennett
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